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Attorneys for Plaintiffs Novo Nordisk Inc. and Novo Nordisk FemCare AG

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK FEMCARE AG, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Novo Nordisk, Inc. and Novo Nordisk FemCare AG (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, "Defendants" or "Sun") allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Sun's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which Sun seeks approval to market a generic version of Novo Nordisk's pharmaceutical product, Vagifem®, prior to the expiration of United States Patent No. 7,018,992 ("the '992 patent"), which covers, inter alia, a method for administering Vagifem®.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of Delaware, and maintains its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

3. Plaintiff Novo Nordisk FemCare AG ("NNFCAG") is an entity organized and existing under the laws of Switzerland, having a place of business at Thurgauerstrasse 36-38, Zurich, Switzerland.

4. On information and belief, Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri Kurla Road, Andheri East, Mumbai 400 059, India. On information and belief, Sun Pharmaceutical Industries Limited is in the business of making and selling generic

pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States. Sun Pharmaceutical Industries Limited has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by filing a lawsuit and asserting counterclaims filed in the United States District Court for the District of New Jersey.

5. On information and belief, Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Defendant Sun Pharmaceutical Industries, Ltd. Sun Pharmaceuticals Industries, Inc. has submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by asserting counterclaims filed in the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Sun by virtue of, inter alia, Sun's presence in New Jersey, having conducted business in New Jersey and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of New Jersey.

8. This Court also has specific jurisdiction over this matter. Sun filed an ANDA with the FDA and sent notice of its paragraph IV certification to Novo Nordisk in New

Jersey. Sun's act of filing its ANDA and sending notice of its paragraph IV certification each provide sufficient minimum contacts with the State of New Jersey under a specific jurisdiction analysis.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

10. On March 28, 2006, the United States Patent and Trademark Office issued the '992 patent,[1] entitled "Hormone Composition," a copy of which is attached to this Complaint as Exhibit A. At the time of its issue, the '992 patent was assigned to Novo Nordisk A/S. NNFCAG currently is the owner of all right, title, and interest in and to the '992 patent. NNI and NNFCAG are indirect, wholly owned subsidiaries of Novo Nordisk A/S.

VAGIFEM®

11. NNI holds approved New Drug Application No. 20908 ("the Vagifem® NDA") for estradiol vaginal tablets, in a 10 mcg dosage strength, which NNI sells under the trade name Vagifem®.

12. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the '992 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Vagifem®.

SUN'S ANDA

13. On information and belief, Sun has submitted ANDA No. 208063 ("Sun's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to sell, offer to

[1] On October 24, 2012, NNFCAG filed a reissue application which is pending as United States Application No. 13/659,605.

sell, use, and/or engage in the commercial manufacture of generic estradiol vaginal tablets in a 10 mcg dosage strength ("Sun's Product").

14. On information and belief, Sun's ANDA refers to and relies upon the Vagifem® NDA and contains data that, according to Sun, demonstrate the bioequivalence of Sun's Product and Vagifem®.

15. By letter to NNI and NNFCAG, dated December 31, 2014, Sun stated that Sun's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '992 patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, or sale of Sun's Product (the "Paragraph IV Certification"). Sun attached a memorandum to its December 31, 2014 letter, in which it alleged factual and legal bases for its Paragraph IV Certification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,018,992

16. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-15 of this Complaint.

17. Defendants have infringed the '992 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sun's ANDA, by which Sun seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sun's Product prior to the expiration of the '992 patent.

18. Defendants' sale, offer for sale, use, or commercial manufacture, of Sun's Product within the United States, or importation of Sun's Product into the United States, during the term of the '992 patent would infringe at least claims 7, 8, 9, 11, and 12 of the '992 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

19. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '992 patent.

20. Plaintiffs have no adequate remedy at law.

21. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that Defendants have infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that the manufacture, use, sale, or offer for sale of Sun's Product will infringe the '992 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Sun's Product within the United States, or importing Sun's Product into the United States, prior to the expiration of the '992 patent, including any extensions;

D. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 208063, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '992 patent, including any extensions;

E. If Defendants commercially manufacture, use, offer to sell, or sell Sun's Product within the United States, or import Sun's Product into the United States, prior to the expiration of

the '992 patent, including any extensions, a judgment awarding Novo Nordisk monetary relief, together with interest;

F. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such other relief as the Court deems just and proper.

Dated: February 12, 2015
Newark, New Jersey

Respectfully submitted,

By: /s/ David E. De Lorenzi

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